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In re application of: DANIEL R. KURZ.
Entitled: INTRAVASCULAR DEVICE PUSH WIRE DELIVERY SYSTEM
Appln. No. 09/625,627
Filed: July 25, 2000
Date Mailed: February 12, 2001
Client ID/Dkt. No. MICRU-55322
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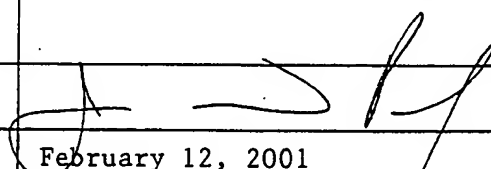
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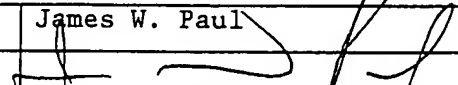
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	Filing Date	July 25, 2000	
	First Named Inventor	Daniel R. Kurz	
	Group Art Unit	3731	
	Examiner Name	W. Lewis	
Total Number of Pages in This Submission	9	Attorney Docket Number	MICRU:55322

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DANIEL R. KURZ

Serial No. 09/625,627

Filed: July 25, 2000

For: INTRAVASCULAR DEVICE PUSH
WIRE DELIVERY SYSTEM

Date: February 12, 2001

Examiner: W. Lewis

Group Art Unit 3731

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James W. Paul, Reg. No. 29,967
Attorney for Applicant

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Washington, D.C. 20231

Sir:

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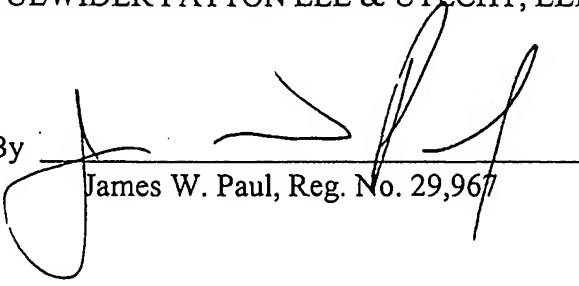
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By


James W. Paul, Reg. No. 29,967

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1 Cited Prior Art Reference

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		Application Number	09/625,627
		Filing Date	July 25, 2000
		First Named Inventor	Daniel R. Kurz
		Group Art Unit	3731
Examiner Name			
Sheet	1	of	1
		Attorney Docket Number	MICRU-55322

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		RETRIEVABLE GIANTURCO-COIL INTRODUCER, By Jeffrey Hawkins, Ronald G. Quisling, MD, J. Parker Mickie, MD an Irvin F. Hawkins, MD (Radiology 1986) From the Depts. Of Radiology and Neurosurgery, University of Florida Medical Center and Hawk Prototype Equipment, Gainesville, FL	

Examiner Signature		Date Considered	
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Discussion

A technique for arterial embolectomy using a balloon embolectomy catheter was first introduced in 1963 (1), and this technique has become recognized as the primary treatment for recent emboli in the lower extremities. We recommend the percutaneous use of this technique as an alternative to thrombolytic therapy (2, 3), catheter aspiration techniques (2, 4), or surgical embolectomy when PTA is complicated by embolism. The risk of subintimal passage of a balloon catheter in a recently dilated artery was thought to be reduced using this technique with physiologic arterial pressure distending the vessel; during these procedures there was no resistance to antegrade passage of the embolectomy catheters. Care was taken not to overdilate the balloon in the recently dilated arterial segment when retrieving the emboli. A

large arterial sheath (9 F) was used to accept the emboli and inflated balloon. Since these procedures were performed, we have used an open-ended sheath with a Y-shaped rotating hemostatic valve (Advanced Cardiovascular Systems, Mountain View, Calif.) to retrieve emboli without having to cut and replace the sheath. Embolectomy should be more effective than thrombolytic therapy when PTA is complicated by atheroemboli on which thrombosis forms. Fogarty embolectomy catheters are frequently used without fluoroscopy during surgery. However, the tips of these catheters can be seen with fluoroscopy, and they are used more efficiently with fluoroscopy and arteriography. Dilated superficial femoral arteries were widely patent by arteriography at the end of the embolectomy procedures, although the potential adverse effects of balloon em-

bolectomy on long-term patency of recently dilated arteries is unknown. We do not recommend the percutaneous use of balloon embolectomy catheters in situations where standard surgical embolectomy and/or vascular reconstruction is established treatment. ■

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Retrievable Gianturco-Coil Introducer¹

Jeffrey Hawkins
Ronald G. Quisling, MD
J. Parker Mickle, MD
Irvin F. Hawkins, MD

A new delivery system for placement of Gianturco coils has been devised that permits retrieval of the coil if malposition occurs. The delivery system itself consists of a very fine coaxial cannula that will cut the monofilament once the coil is properly placed. It has been successfully used on three patients in whom a total of 48 coils were employed to occlude great vein of Galen aneurysms. The system is applicable for routine coil embolization but has particular application in treating high-flow vascular lesions (arteriovenous fistulas or malformations).

Index terms: Arteries, therapeutic blockade • Veins, Galen, 1765.73 • Veins, therapeutic blockade

Radiology 1986; 158:262-264

TREATMENT of high-flow arteriovenous fistulas requires tailoring of the methods to fit the characteristics of the target. Use of intravascular steel-Dacron coils has become accepted practice for many lesions (1-4). Treatment of high-flow fistulas associated with a vein of Galen aneurysm has proved especially difficult both for interventional neuroradiographic techniques and for direct surgical excision. To approach such lesions from the venous side of the fistula, a specialized introducer was needed that would allow the operator to retrieve the embolized coil if it could not be positioned optimally within an aneurysm in the vein of Galen. This particular application spurred the development of this coil-introducing system. It should be stressed that this procedure is still in the early stages of investigation. The risks inherent in the transthoracic treatment of high-flow fistulas are as yet unknown since this approach has been used in only a few patients. Venous occlusion of other high-flow states such as carotid-cavernous fistulas, however, has been highly successful without producing significant morbidity.

Materials and Methods

Technical description.—This device uses a 16-cm-long intravascular embolization steel coil of the Gianturco type (Cook Inc., Bloomington, Ind.) loaded within a 20-cm metal sheath. Fitting inside the coil loader is a specialized coaxial introducer system composed of a 25-gauge inner cannula to which is

added a distal cutting block. Fitting around this is a 21-gauge outer cannula, the distal margin of which has cutting capability. A monofilament (4-lb test, 0.008 inch) passes through the inner cannula exiting via a side hole located just proximal to the cutting block. The monofilament is attached to the Gianturco coil. Retraction of this monofilament allows an already extruded coil to be returned to the sheath and ultimately to the loading cannula from which it can easily be repositioned or removed.

Technique.—A percutaneous puncture of a vessel is made, and a guide wire is positioned at the target. A 6.5-F polyethylene sheath catheter is placed over the guide wire and positioned optimally for embolization. The introducer system is passed through a Touhy-Borst adaptor. The coil-loading portion of the cannula stops in the hub of the catheter. The thinner metal coaxial cannulas, which contain the monofilament attached to the coil, are then pushed inward forcing the coil out of the embolization catheter and into the target. The embolization catheter should always be advanced as closely as possible to the target site. If the embolized coil moves away from the target or into an inappropriate position, retraction of the monofilament results in return of the coil to the catheter sheath. When the coil is correctly placed, the outer cannula is unlocked and rotated, which results in its moving forward and transecting the monofilament. The entire introducer system is then removed,

Figure illustrates Gianturco coil embolization technique. The introducer system is passed through a Touhy-Borst adaptor. The coil-loading portion of the cannula stops in the hub of the catheter. The thinner metal coaxial cannulas, which contain the monofilament attached to the coil, are then pushed inward forcing the coil out of the embolization catheter and into the target. The embolization catheter should always be advanced as closely as possible to the target site. If the embolized coil moves away from the target or into an inappropriate position, retraction of the monofilament results in return of the coil to the catheter sheath. When the coil is correctly placed, the outer cannula is unlocked and rotated, which results in its moving forward and transecting the monofilament. The entire introducer system is then removed.

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¹ From the Departments of Radiology (R.G.Q., I.H.) and Neurosurgery (J.P.M.), University of Florida Medical Center and Hawk Prototype Equipment (J.H.), Gainesville, Fla. Received February 14, 1985; accepted and revision requested April 9; revision received May 10. Address reprint requests to R.G.Q., Department of Radiology, Box J-374 JHMHC, Gainesville, FL 32610.

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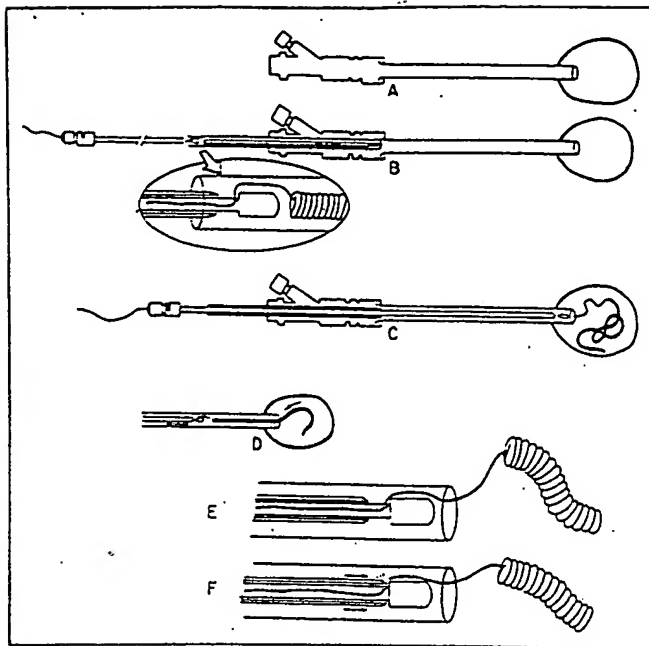


Figure 1. Embolization procedure. (A) The polyethylene embolization catheter is fluoroscopically directed into the target (circle). It has a Touhy-Borst adapter proximally to minimize blood loss during the procedure. (B) The Gianturco-coil loader is first introduced into the embolization catheter and then advanced toward the target using the coaxial metal cannulas containing the monofilament. The insert demonstrates the relationship of the monofilament to the inner cannula, which has the cutting block attached, and the outer cannula with its distal cutting edge. The monofilament attaches to the posterior aspect of the Gianturco coil. (C) The coaxial catheter is used to push the coil out of the catheter into the target. (D) If the coil position is unsatisfactory, it can be returned by retraction of the monofilament. (E) If the coil position is satisfactory, the outer sleeve of the coaxial metal cannula is slipped over the inner sleeve until its cutting edge engages the cutting block. (F) A twisting motion is then made to cut the monofilament. After the monofilament is detached, the entire coaxial system is removed, and the next wire can be introduced through the embolization catheter, which has remained in place.

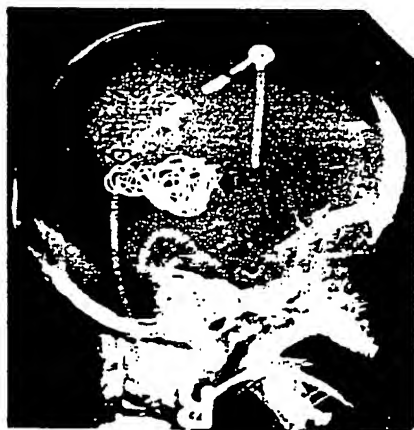


Figure 2. Lateral skull radiograph illustrates the postembolic state after modified Gianturco coils were deposited via a percutaneous approach into a vein of Galen aneurysm. Following percutaneous catheterization of the superior sagittal sinus, the outer catheter was manipulated into the straight sinus and subsequently into the vein of Galen. Embolization wires were introduced into the lumen of the vein of Galen aneurysm (solid arrow) and proximal straight sinus (open arrow) until a reduction in venous pressure was noted at the puncture site in the superior sagittal sinus. Prior to embolization, this patient had a thorough evaluation of the flow dynamics and morphologic features of this lesion with computed tomography and angiography. A return to more normal cerebral blood flow was documented by Doppler ultrasound studies of the deep jugular venous system. Following coil embolization, significant improvement was noted in the patient's clinical status.

leaving the embolization catheter in place (Fig. 1). Another coil can then be introduced depending on the change in vascular dynamics. After each wire was correctly positioned and detached,

Table 1
Coil Deposition Staging

Patient No.	No. First Stage	No. Second Stage	Total
1	4	12	16
2	5	12	17
3	6	8	14

the natural tendency of the wires to expand provided the means to ensure that the coil would remain applied against the wall of the aneurysm. Since the aneurysms were larger in cross-sectional diameter than the straight sinus, there was no observed movement of the coils from the target to the straight sinus or torcula. In addition, the wires became entangled as more were introduced (Fig. 2). Eventually a wire mesh was created. These two factors ensured that the embolic wires would stay in the target and not undergo distal migration. As the embolization procedure continued, the distention of the exposed torcula was observed to decrease. This provided a direct means of monitoring the course and success of the procedure.

Results

A total of 48 coils were embolized successfully in three patients. The procedure was staged in all three cases. The distribution of coils is presented in Table 1. An initial embolization with approximately eight coils was used followed by additional embolization within 1 week for the remainder of the coils. During the embolizations, five coils were misdirected, entering thala-

moperforating arteries. In each instance they were easily retrieved and subsequently repositioned before being detached. The monofilament was easily transected without dislodging the coil in all instances. Only minimal blood loss occurred during insertion of the coils. The coils either reduced flow or totally occluded the aneurysms in all three cases. Clinical details will be included in a subsequent publication.

Discussion

Certain high-flow vascular lesions, such as vein of Galen aneurysms, have proved to be particularly difficult to treat by either direct surgical approach or by interventional neuroradiographic means. Stainless steel coils and baffles have been used to control blood flow in a variety of other lesions, both in clinical practice and under experimental conditions (2-4). There is always the danger of coils passing through a high-flow fistula and embolizing the pulmonary circulation (5). To detect inadvertent migration of embolized wires prior to their release, a specialized introducer system was devised that maintains continuity with an embolized coil via a nylon monofilament. In the three clinical cases, migration of the coils into the confluence of venous sinuses (torcula) could have acutely raised intracranial pressure. The use of this system ensured stability of the coil prior to severing the monofilament and thereby avoided coil movement into the torcula. This device allowed assessment of the status of the coil within the embolization target prior to irrevocable release. It is also extremely important to detach the monofilament without moving the coil. The present system transects the monofilament without retract-

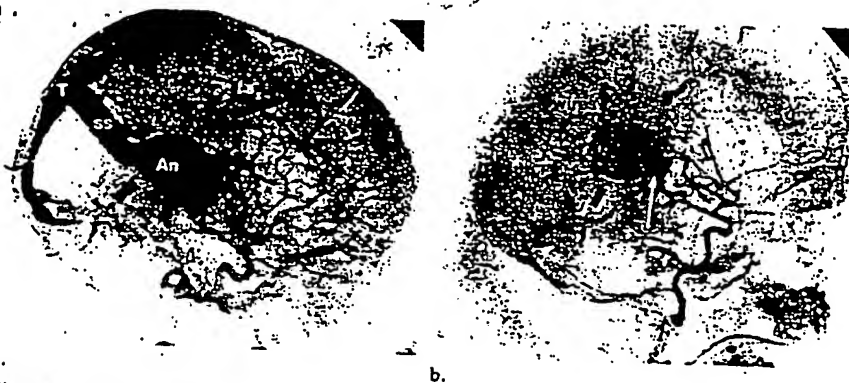


Figure 3. (a) Preembolization lateral projection carotid angiogram demonstrates filling of the vein of Galen aneurysm (An), as well as ectasia of the straight sinus (ss) and a high position of the torcula herophila (T). The arteriovenous malformation associated with the venous abnormality is imaged as the capillary tangle of vessels surrounding the anteroinferior aspect of the vein of Galen aneurysm. (b) Postembolization lateral projection carotid angiogram obtained 3 months after embolic treatment with this Gianturco-coil introducing system demonstrates no filling of the vein of Galen aneurysm or straight sinus. A small residual vascular malformation persists (arrow), which subsequently fills into choroidal veins. A substantial portion of the vascular malformation, as well as the vein of Galen aneurysm, has been eradicated by the coil embolization. The mass of wires is apparent within the vein of Galen and proximal straight sinus region (compare with a).

ing it, thereby preventing positional changes of the coil within the target or precipitating migration from the non-target area. The present system is moderately flexible with an ability to negotiate an approximately 90° turn within the outer embolization catheter. Clinical use to date has not required significant bending of the cannulas. For general vascular embolization, however, a more flexible system may be required. Presently, the same principle is being adapted to a guide wire system that

will be as flexible as a standard 0.035 guide wire.

It should be noted that a transtorcular approach to such high-flow fistulas has not been considered a feasible alternative. However, use of vascular balloon catheters for high-flow fistulas such as carotid-cavernous fistulas has proved to be highly successful. In this instance, the balloon occludes a major dural sinus. The chronic nature of such a high-flow state alters the dependence of the cranial circulation to that par-

ticular route. This has become evident with the extensive intraarterial balloon occlusion work (6). The transtorcular venous catheterization and embolization for vein of Galen fistulas were carefully monitored during the procedure for venous pressure and clinical status. Additionally, the procedure was staged into two parts (Fig. 3). Partial occlusion was achieved first, and the subsequent embolization was used for final completion of the venous occlusion. Blood flow was monitored after each procedure and in the subsequent follow-up period by Doppler ultrasound. ■

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Congenital Heart Disease: Gated MR Imaging in 72 Patients / 227

Dominique Didier, Charles B. Higgins, Madeleine R. Fisher, Luci Osaki, Norman H. Silverman, and Melvin D. Cheitlin

Twin and Singleton Growth Patterns Compared Using US / 237

Kathryn Grumbach, Beverly G. Coleman, Peter H. Arger, Marshall C. Mintz, Steven V. Gabbe, and Michael T. Mennuti

Hydrothorax, Ascites, and Right Diaphragmatic Hernia / 243

Vicente Gilsanz, Dieter Emons, Manfred Hansmann, Morteza Meradji, James S. Donaldson, Felix Omenaca, Jose Quero, and Bernard L. Tucker

Medical Physics

High-Resolution MR Imaging Using Loop-Gap Resonators. Work in Progress / 247

J. Bruce Kneeland, A. Jesmanowicz, W. Froncisz, Thomas M. Grist, and James S. Hyde

Technical Developments and Instrumentation

Patient Immobilization during CT for Treatment Planning of Head and Neck Cancer / 251

Wilfred Sewchand, Cengiz Aygun, Geraldine Nicholson, and Omar M. Salazar

Left Ventricular Function Evaluation Using Radionuclide Methods in the Intensive Coronary Care Unit / 252

Andries van Aswegen, Anton C. Otto, Charles P. Herbst, Jan D. Marx, Pieter H.T. Kleynhans, Mattheus G. Lötter, and Phillip C. Minnaar

Carotid Artery Disease: New Criteria for Evaluation by Sonographic Duplex Scanning / 253

Uri Vaisman and Marc Wojciechowski

Intraarterial Digital Subtraction Arteriographic Evaluation of Extremity Tumors: Comparison with Conventional Arteriography / 255

Kyo Rak Lee, Glendon G. Cox, Hilton I. Price, Joy A. Johnson, and James R. Neff

Contrast Medium Precipitation during Abdominal CT / 258

David S. Ball, Paul D. Radecki, Arnold C. Friedman, Dina F. Caroline, and David P. Mayer

Balloon Embolectomy Catheter Used Percutaneously / 260

James J. Zimmerman, Paul R. Cipriano, William G. Hayden, and Thomas J. Fogarty

Retrievable Gianturco-Coil Introducer / 262

Jeffrey Hawkins, Ronald G. Quisling, J. Parker Mickle, and Irvin F. Hawkins

Editorials

Radiology 1986 / 265

Stanley S. Siegelman

Manuscript Processing at the RSNA Publications Office / 267

Roberta E. Arnold

Helen C. Redman

James J. McCort, MD: President, Radiological Society of North America, 1986 / 272

Henry P. Pendergrass

Opinion

Digital Projection Radiography of the Chest / 274

Harold L. Kundel

Letters to the Editor

Re: The Thyroid Gland with Low Uptake Lesions: Evaluation by Ultrasound / 277

Otmar Schober and Rudiger Schwarzrock

Reply / 277

Luigi Solbiati, Luca Volterrani, Giorgio Rizzatto, Massimo Bazzocchi, Paolo Busilacchi, Francesco Candiani, Francesco Ferrari Gianmarco Giuseppetti, Giulia Maresca, Paola Mirk, Leopoldo Rubaltelli, and Franco Zappasodi

Re: Integrated Imaging of Hepatic Tumors in Childhood / 278

S. Neuenschwander, D. Couanet, and J. Ph. Montague

Reply / 278

John H. Miller and Bennett S. Greenspan

Re: Magnetic Resonance Imaging of Prosthetic Heart Valves / 279

Renate L. Soulen

Notice to the Readership / 279

Abstracts of Current Literature

Contents / 281

Abstracts and Author Summaries / 281

Book Reviews

Echotomographie et Pathologie Thoracique [Ultrasound of thoracic disease] / 20

Georges Aimino

Reviewed by Alan E. Oestreich

Galliumszintigraphie - Diagnostik bei entzündlichen Erkrankungen und Tumoren [Gallium scintigraphy in inflammatory disease and tumor diagnosis] / 34

Hanno Botsch

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First Named Inventor	Daniel R. Kurz
Examiner Name	W. Lewis
Group Art Unit	3731
Attorney Docket No.	MICRU:55322

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107 490	207 245	Plant filing fee	
108 710	208 355	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$)

2. EXTRA CLAIM FEES

Extra Claims Fee from below Fee Paid

Total Claims -20** = X =

Independent Claims -3** = X =

Multiple Dependent =

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
103 18	203 9	Claims in excess of 20
102 80	202 40	Independent claims in excess of 3
104 270	204 135	Multiple dependent claim, if not paid
109 80	209 40	** Reissue independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	
139 130	139 130	Non-English specification	
147 2,520	147 2,520	For filing a request for ex parte reexamination	
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	
115 110	215 55	Extension for reply within first month	
116 390	216 195	Extension for reply within second month	
117 890	217 445	Extension for reply within third month	
118 1,390	218 695	Extension for reply within fourth month	
128 1,890	228 945	Extension for reply within fifth month	
119 310	219 155	Notice of Appeal	
120 310	220 155	Filing a brief in support of an appeal	
121 270	221 135	Request for oral hearing	
138 1,510	138 1,510	Petition to institute a public use proceeding	
140 110	240 55	Petition to revive - unavoidable	
141 1,240	241 620	Petition to revive - unintentional	
142 1,240	242 620	Utility issue fee (or reissue)	
143 440	243 220	Design issue fee	
144 600	244 300	Plant issue fee	
122 130	122 130	Petitions to the Commissioner	
123 50	123 50	Processing fee under 37 CFR 1.17(q)	
126 180	126 180	Submission of Information Disclosure Stmt	180
581 40	581 40	Recording each patent assignment per property (times number of properties)	
146 710	246 355	Filing a submission after final rejection (37 CFR § 1.129(a))	
149 710	249 355	For each additional invention to be examined (37 CFR § 1.129(b))	
179 710	279 355	Request for Continued Examination (RCE)	
169 900	169 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$)

SUBMITTED BY

Complete (if applicable)

Name (Print/Type) **James W. Paul**Registration No. (Attorney/Agent) **29,967**Telephone **310/824-5555**

Signature

Date **Feb. 12, 2001**

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